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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,031	12/11/2003	Linda Bootland	10044	8423

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EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/733,031	Applicant(s) BOOTLAND ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 24-42 is/are pending in the application.
- 4a) Of the above claim(s) 33-39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 24-32, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 5 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's amendment filed June 23, 2006. In view of the newly added claims, the following restriction applies.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 24-32, 40 and 41, drawn to a plant expressing a fish antigen, classified in class 800, subclass 295.
- II. Claims 33-39, 42 and 43, drawn to a method of using a plant, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the plant can be used to make the protein of interest to be isolated and purified.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-10 and 24-42 are pending. Claims 1-10, 24-32 and 40-41 are elected by original presentation. Claims 33-39, 42 and 43 are withdrawn from examination as being drawn to a non-elected invention.

All previous rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6-9, 24-32, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman (US Pat. No. 4956282 (A) in view of Koprowski et al. (US Pat. No. 5935570 (previously cited)). Goodman teaches the expression of various heterologous proteins in transgenic plants because the expressed protein is properly processed or folded, maintains its physiological activity and is free of deleterious contaminants (col. 1, Ins. 33-45; col. 10, Ins. 11-23). The protein can be expressed in any plant part including seed and the use of a leader signal sequence can direct expression to a particular organelle (col. 2, Ins. 37-40 and 58). The expressed protein includes various antigens (col. 3, Ins. 29-36). The plant can be a monocot (including

corn) or a dicot (col. 4, Ins. 55-62). The transgenic plant expressing the protein can be ingested or eaten to obtain the physiological effect (col. 5, Ins 51-60).

Goodman does not teach a fish antigen.

Koprowski teaches a plant and seed infected with a genetically modified microorganism expressing a fish antigen including from the fish pathogen birnaviridae (col. 7, In. 24) which can be administered with an adjuvant (excipient) (col. 8, In. 2).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to express the fish antigen of Koprowski using the plant expression system of Goodman for the purpose of producing a fish immunogenic composition. The art recognizes various expression systems. Goodman teaches bacterial, yeast, mammalian and plant expression systems (col. 1, Ins. 26-32). Koprowski teaches a genetically modified microorganism infecting a plant which expresses a fish antigen (col. 1, Ins. 55-61). Whether one expresses a fish antigen using the microorganism and plant of Koprowski or the plant of Goodman is a matter of design choice without any surprising or unexpected results. The advantages of using the Goodman system have been discussed above. The plant of Goodman would inherently express the fish antigen at the 0.1% total soluble protein level and would induce an immunogenic response in fish when eaten/ingested by fish. Accordingly, one skilled in the art would have been motivated to do so with a reasonable expectation of success.

Applicant's traversals are not addressed here because the 102(b) rejection has been withdrawn in view of amended claims and do not apply to the above 103(a) rejection.

Remarks

4. Claims 5 and 10 are objected to as being dependent on rejected claims but would be allowable if rewritten in independent form.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Phuong T. Bul". The signature is stylized with a large initial "P" and a cursive "Bul".

Phuong T. Bul
Primary Examiner
Art Unit 1638

9/9/06